INTRODUCTION
Several different types of devices are available to aid in spinal fixation. Clinical results are usually acceptable but aseptic loosening may occur, and may be accompanied by particles of wear debris. Debris is now recognized as a probable cause of loosening of total joint prostheses, but the particles of debris associated with spinal devices, and it's relation to motion are unclear. Wear debris in the spine could be derived from several sources, including fretting and/or corrosion between modular components or from surgical instruments. A few reports describe the tissue reaction to debris around human lumbar fusion implants (1, 2), but to our knowledge no previous studies have quantified particles at this site. The purpose of this study is to use an established segmental spinal fusion model to characterize the relationship between the motion of a spinal segment and the concentration of wear particles in soft tissue surrounding the fixation device.

MATERIALS AND METHODS:
As part of a study comparing different bone substitute materials, a mid-line posterior longitudinal incision was made from T10 - L7 in 20 beagle dogs (9 - 18 months of age), approximately 10 - 15 kg. The interspinous ligament and interlaminar tissues were excised at the L1 - 2, L3 - 4 and L5 - L6 interspaces. Internal fixation at each site consisted of two 316L stainless steel plates fixed on right and left sides of the spinous processes using stainless steel bolts and nuts. After fixation, interfacet fusion was performed, using one of several different bone substitute materials, details of which are not relevant to this study. Dogs were euthanized 12 weeks after surgery and vertebral bodies were removed. The individual segments were separated. Soft tissues were without damage to the fusion site. Computerized Tomography (CT) was obtained after removal of the fixation devices and bone volume and center bone area were determined using special software. Each spinal segment was tested in lateral bending using an electrohydraulic materials testing machine (MTS Systems). Load displacement curves were used to derive stiffness. Biopsies were obtained from tissue around and beneath the plate and screw holes of three fusion sites in each dog, and from around non-operated facets (negative controls) in several dogs. Particles were isolated as previously described (3). Briefly, biopsies were fixed in formalin and routinely processed for light microscopy, and the presence or absence of particles, inflammation and foreign body reaction was noted qualitatively from the microscope slides. The corresponding tissue was then harvested from the paraffin blocks, digested, washed, and particles isolated on Nuclepore filters. Particles were analyzed using an electrical resistance particle analyzer (Coulter Multisizer II) as well as using scanning electron microscopy (SEM) with energy-dispersive x-ray spectroscopy (EDX). Correlations between the results of mechanical testing, particle quantification and quantitative CT were tested using the Pearson product-moment coefficient. P values less than 0.05 were considered statistically significant.

RESULTS:
Most biopsies showed only fibrous tissue with no recognizable macrophages, inflammation or debris. Occasional biopsies, however, contained opaque particles, consistent with metallic wear debris, apparently within macrophages and foreign body giant cells (Fig). The tissue concentration of particles from spinal fusion sites ranged from 0.13 - 22.3 x 10⁶ per gram (dry wt), with a mean of 2.8 x 10⁶ while control biopsies showed 0.49 x 10⁶ particles, presumably undigested biologic material. Particles were small, approaching the lower limit of the detector (0.5 um). SEM with EDX detected particles composed of Fe, Cr and Ni, corresponding to elements found in the metallic fixation hardware. The results of stiffness from mechanical testing ranged from 2.0 - 25.4 N/mm². Quantitative CT scanning showed that bone volume ranged from 559.5 - 2158.6 mm³, and center bone area ranged from 46.3 - 206.8 mm². Statistical analysis showed a significant correlation between the log particle number and stiffness of the spine/hardware construct (r = -0.44, p = 0.01), bone volume (r = -0.28, p = 0.03), and center bone area (r = -0.34, p = 0.01).

DISCUSSION:
Experience with total joint arthroplasty suggests that particles of wear debris may induce an inflammatory reaction that directly or indirectly results in bone resorption and implant loosening. Some types of spinal fixation hardware have many modular connections, and concern has been expressed about potential debris production from these modular interfaces. In this prospective animal study, most fusion sites shaved no evidence of osteolysis and did not have particles higher than background counts seen in control samples. Several fusion sites, however, had a histologic appearance similar to that around loose total joint prostheses, with numerous macrophages, giant cells, and particles visible by light microscopy. Although we detected particles in concentrations similar to biopsies from around failed joint implants in a few sites, we found no obvious evidence of bone resorption. The tissue particle concentration showed a significant correlation with instability of the fusion construct, but with low r values, suggesting a complex relationship between motion, bone volume and particles. Although this study demonstrates particles associated with motion around spinal hardware, further studies are needed to determine whether these particles are of clinical significance.

Reference:

Figure: Photomicrograph showing particles of metallic wear debris, macrophages and giant cells adjacent to spinal fixation hardware.

**INFLUENCE OF FIXATION AND MECHANICAL PROPERTIES OF A SPINAL FIXATION DEVICE ON PRODUCTION OF WEAR DEBRIS PARTICLES IN VIVO**

*Mochida Y, Nito H, +Bauer TW, Muschler GF. Dept. of Anatomic Pathology and Orthopaedic Surgery, The Cleveland Clinic Foundation, 9500 Euclid Ave, Cleveland, Ohio 44195, USA. Phone: 216-4446830, Fax: 216-4459976, e-mail: osteoclast@aol.com*